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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 710

[EPA-HQ-OPPT-2018-0320; FRL-10001-44]

RIN 2070-AK21

Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory; Revisions to the CBI Substantiation Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: In response to a recent federal circuit court decision, EPA is proposing revisions to existing and proposed substantiation requirements for certain confidential business information (CBI) claims made under the Toxic Substances Control Act (TSCA). Specifically, EPA is proposing two additional questions that manufacturers and processors would be required to answer to substantiate certain CBI claims for specific chemical identities; and is proposing procedures for manufacturers and processors to use in amending certain previously-submitted substantiations to include responses to the additional questions. These proposed revisions supplement the proposed rule issued in the **Federal Register** of April 23, 2019, and would amend the TSCA Inventory Notification (Active-Inactive) Requirements rule promulgated in the **Federal Register** of August 11, 2017.

DATES: Comments must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0320, by one of the following methods:

• *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Scott M. Sherlock, Environmental Assistance Division (Mail code 7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-8257; email address: sherlock.scott@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be affected by this action if you reported a confidential chemical substance

under the TSCA Inventory Notification (Active-Inactive) Requirements rule (hereinafter “Active-Inactive Rule”) (Ref. 1) (40 CFR part 710, subpart B) through a Notice of Activity (NOA) Form A (Ref. 2) or NOA Form B (Ref. 3) and sought to maintain an existing CBI claim for a specific chemical identity. You may also be affected by this action if you anticipate reporting a confidential chemical substance under the Active-Inactive Rule through an NOA Form B in the future, and anticipate seeking to maintain an existing CBI claim for a specific chemical identity at that time. The following North American Industrial Classification System (NAICS) codes are not intended to be exhaustive, but rather provides a guide to help readers determine whether this action may apply to them:

- Chemical manufacturing or processing (NAICS code 325).
- Petroleum and Coal Products Manufacturing (NAICS code 324).

“Manufacture” is defined by TSCA section 3(9) (15 U.S.C. 2602(9)) and 40 CFR 710.3(d) to include “import.” Accordingly, all references to manufacturers in this document should be understood to include importers.

If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

EPA is proposing this rule pursuant to the authority in TSCA section 8(b), 15 U.S.C. 2607(b). See also Units I.B and II.B in EPA’s proposed rule entitled “Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory,” issued in the *Federal Register* of April 23, 2019 (hereinafter “2019 Proposed Rule”) (Ref. 4), which proposed provisions to be codified in 40 CFR 710, subpart C.

C. What action is the Agency taking?

EPA is supplementing the 2019 Proposed Rule (Ref. 4), which proposed to use the same CBI substantiation questions that were promulgated in the Active-Inactive Rule (Ref. 1) and codified in 40 CFR 710, subpart B. EPA is now proposing to revise the substantiation questions promulgated in the Active-Inactive Rule. See the discussions in Unit II.

As discussed in more detail in Unit III., this supplemental proposed rule presents two additional questions that EPA is proposing manufacturers and processors would be required to answer to substantiate CBI claims for specific chemical identities asserted in an NOA Form A or B. To ensure that EPA receives sufficient information to review and approve or deny all specific chemical identity CBI claims asserted in an NOA Form A or B, EPA is also proposing procedures for manufacturers and processors to use in supplementing previously-submitted substantiations to include responses to the additional questions.

D. Why is the Agency taking this action?

In response to the federal circuit court decision that is discussed in more detail in Unit II.C., EPA is reconsidering the inclusion of substantiation questions directly related to a chemical identity's susceptibility to reverse engineering. Because the 2019 Proposed Rule specifically references the substantiation questions promulgated in the Active-Inactive Rule that were subsequently subject to the federal court decision, EPA believes it is most efficient and straightforward to address the substantiation questions for both rules in this supplemental proposed rule. This will allow stakeholders to submit a single set of comments pertaining to EPA's inclusion of substantiation questions regarding reverse engineering in light of the federal court's decision and supports EPA's efforts to maintain consistency in the manner by which these two closely related rules address the issue. EPA intends to consider comments received and finalize amendments to the existing substantiation questions in 40 CFR 710, subpart B as part of

the final rule promulgating 40 CFR 710, subpart C.

E. What are the estimated incremental impacts of this action?

EPA has evaluated the potential costs of adding two additional questions related to substantiation of CBI claims for specific chemical identity to the 2019 Proposed Rule and the previous Active-Inactive Rule. A memorandum outlining the estimated costs, entitled “Burden and Cost Estimates for the Supplemental Notice of Proposed Rulemaking: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory” (Ref. 5), has been prepared for this supplemental proposed rule, is available in the docket, and is briefly summarized here. The incremental change to requirements involves the reporting activity of addressing two additional CBI substantiation questions, which is an activity similar to those already included in the Active-Inactive Rule and in the 2019 Proposed Rule.

1. *Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory (proposed subpart C of 40 CFR part 710, as proposed to be amended by this supplemental proposed rule).* As explained in Unit I.E of the 2019 Proposed Rule, companies potentially affected by the 2019 Proposed Rule fall into three groups of reporters who made a CBI claim for a specific chemical identity in their NOA Form A. Group (1) consists of those reporters who already voluntarily submitted substantiation as part of the NOA Form A submission process and who will now need to supplement their substantiations. Group (2) consists of those reporters who would be eligible to reference some other previous substantiation made to EPA within the last five years, exempting them from the requirement to submit new substantiation. Group (3) consists of those reporters who would be required to submit a full substantiation as they did not previously substantiate the claim, either as part of the NOA Form A voluntary substantiation process, or as part of some other submission within the last five years.

Under this supplemental proposed rule, Groups (1) and (3) would be required to submit responses to the two proposed additional substantiation questions. There would be no additional requirements for Group (2).

2. *Active-Inactive Rule (subpart B of 40 CFR part 710, as proposed to be amended by this supplemental proposed rule).* Under the requirements of the Active-Inactive Rule, as proposed to be amended by this supplemental proposed rule, all reporters who assert a CBI claim for specific chemical identity in their NOA Form B would be required to address the two proposed additional substantiation questions. As detailed in the Active-Inactive rule at 40 CFR 710.25(c) and 710.27, reporters submitting an NOA Form B are those who intend to manufacture or process for nonexempt purposes a chemical substance designated as inactive on the TSCA Inventory. Note that Form B reporting is ongoing, compared to the one-time reporting associated with Form A.

3. *Total estimated incremental impacts.* Table 1 summarizes the incremental impacts of the supplemental proposed rule for each group according to Form/rule/ICR. The incremental increase in unit burden for the two additional substantiation questions is estimated at 0.19 hours per affected chemical-specific submission. Total incremental burden for one-time reporting on NOA Form A is 1,123 hours with associated cost of approximately \$87,000 per year; total incremental burden for reporting on NOA Form B is 0.4 hours per year with associated cost at about \$29 per year.

Table 1: Incremental Impacts of Supplemental Proposed Rule

Rule/Form	Frequency	Respondents	Responses (chemical- specific submissions)	Burden (Hours)	Cost (2018\$)
Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory					
Form A Group (1) –	One-time	149	3,137	595	\$46,090

Submissions Supplementing Voluntary Upfront CBI Substantiation					
Form A Group (2) – Submissions with CBI Substantiation Using Reference	One-time	23	98	0	\$0
Form A Group (3) – Submissions with Full CBI Substantiation	One-time	103	2,751	528	\$40,964
TOTAL, Form A		275		1,123	\$87,054
Active-Inactive Rule					
Form B - Submissions with Full CBI Substantiation	Annual	1	2	0.4	\$29

F. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI in a CD-ROM or other electronic media that you mail to EPA, mark the outside of the media as CBI and then identify electronically within the media the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2, subpart B.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets.html>.

II. Background

A. *What is the Active-Inactive Rule?*

TSCA section 8(b) requires EPA to designate chemical substances on the TSCA Chemical Substance Inventory as either “active” or “inactive” in U.S. commerce. To accomplish that, the 2017 Active-Inactive Rule (Ref. 1), codified in 40 CFR part 710, subpart B, established

a retrospective electronic notification of chemical substances on the TSCA Inventory that were manufactured (including imported) for nonexempt commercial purposes during the 10-year time period ending on June 21, 2016, with provision to also allow notification by processors. EPA used these notifications—filed on an NOA Form A—to distinguish active substances from inactive substances, and now includes the active and inactive designations on the TSCA Inventory. The Active-Inactive Rule also established procedures for forward-looking electronic notification of chemical substances on the TSCA Inventory that are designated as inactive, if and when the manufacturing or processing of such chemical substances for nonexempt commercial purposes is expected to resume. On receiving forward-looking notification, which is filed on an NOA Form B, EPA will change the designation of the pertinent chemical substance on the TSCA Inventory from inactive to active. The one-time submission period for NOA Form A ended on October 5, 2018, while the NOA Form B will be submitted on an ongoing basis.

Consistent with TSCA sections 8(b)(4)(B)(ii) and (5)(B)(ii), the Active-Inactive Rule provided that manufacturers and processors filing an NOA Form A or B could seek to maintain an existing claim for protection against disclosure of the specific chemical identity of a chemical substance as confidential by including such a request on their NOA Form A or B. Through this process established in 40 CFR 710.37(a), manufacturers and processors secured an opportunity to maintain the CBI status of a specific chemical identity on the confidential portion of the TSCA Inventory. The Active-Inactive Rule required NOA Form B submitters to substantiate these CBI claims not later than 30 days after submitting their NOA Form B by answering substantiation questions set forth in the Rule and codified at 40 CFR 710.37(c). The Rule also permitted NOA Form A submitters to voluntarily substantiate their CBI claims for specific chemical identities at the time of filing their NOA Form A by answering the same substantiation questions. The

Active-Inactive Rule did not require NOA Form A submitters to substantiate these CBI claims because TSCA section 8(b)(4)(C) directed EPA to promulgate another rule addressing the substantiation and review of those claims.

B. What is the 2019 Proposed Rule?

On April 23, 2019, EPA proposed to establish a plan to review all CBI claims for specific chemical identities asserted in an NOA Form A, including the procedures for substantiating and reviewing those claims (Ref. 4). The 2019 Proposed Rule was presented as a follow-on rulemaking to the 2017 Active-Inactive Rule. See detailed background in Unit II. of the 2019 Proposed Rule (Ref. 4). As such, it specifically referenced the substantiation questions for specific chemical identity CBI claims that had been promulgated in the Active-Inactive Rule and codified at 40 CFR 710.37(c), i.e., proposing to require manufacturers and processors who had submitted an NOA Form A requesting to maintain an existing CBI claim for a specific chemical identity to substantiate that CBI claim by submitting answers to the substantiation questions in 40 CFR 710.37(c). Manufacturers and processors who had already submitted answers to those substantiation questions pursuant to the voluntary process established in the Active-Inactive Rule would have been exempt from any further substantiation requirements under the 2019 Proposed Rule. Manufacturers and processors who had provided substantiations for specific chemical identity CBI claims in another submission made to EPA less than five years before the substantiation deadline that would be set in the final rule, would also have been exempt from further substantiation requirements under the 2019 Proposed Rule, provided that they reported to EPA certain identifying information about the previously submitted substantiation (submission date; submission type; and case number, transaction ID, or equivalent identifier that would uniquely identify the previous submission that contained the substantiation).

C. What is the Federal Circuit Court Decision?

On April 26, 2019, the U.S. Court of Appeals for the District of Columbia Circuit entered a judgment in *Environmental Defense Fund v. EPA*, 922 F.3d 446 (D.C. Cir. 2019), granting in part and denying in part a petition for review of the Active-Inactive Rule. The court ordered a limited remand of the Active-Inactive Rule, without vacatur, for EPA “to address its arbitrary elimination of substantiation questions regarding reverse engineering.” 922 F.3d at 459. Citing the statutory requirements at TSCA section 14(c)(1)(B)(iv) and (c)(3) that a person asserting a CBI claim must include a statement that the person has “a reasonable basis to believe that the information is not readily discoverable through reverse engineering,” and must “substantiate the claim,” the court found that EPA’s “omission of any inquiry into a chemical identity’s susceptibility to reverse engineering effectively excised a statutorily required criterion from the substantiation process.” *Id.* at 454. Because the Active-Inactive Rule did not explain the gap in substantiation or acknowledge the consequence of the omission, the court found the Active-Inactive Rule to be arbitrary and capricious to the extent that it omitted any substantiation requirement pertaining to reverse engineering. *Id.* The court remanded the Active-Inactive Rule to EPA without vacatur, leaving all provisions of the Active-Inactive Rule in effect while EPA conducts further proceedings on remand. A copy of the court’s opinion is available in the docket for this action.

III. Summary of Proposed Revisions

In response to the court’s remand and discussed in detail in this unit, EPA is proposing to amend 40 CFR 710.37(c) to include two additional substantiation questions related to a specific chemical identity’s susceptibility to reverse engineering. These substantiation questions would apply to manufacturers and processors who request(ed) to maintain a CBI claim for a specific

chemical identity in either an NOA Form A or an NOA Form B. EPA is also proposing to require any manufacturer or processor who has already submitted answers to the substantiation questions currently listed in the Active-Inactive Rule at 40 CFR 710.37(c) to supplement their submission by adding answers to the newly proposed questions relating to reverse engineering. Finally, EPA is proposing to revise the proposed substantiation exemption for NOA Form A submitters who have previously submitted a substantiation outside of the Active-Inactive Rule process, to clarify that this proposed exemption would apply only where the previously submitted substantiation is responsive to all substantiation questions in 40 CFR 710.37(c) as amended by the final rule to the 2019 Proposed Rule.

A. What additional substantiation questions is EPA proposing?

To solicit additional information about a specific chemical identity's susceptibility to reverse engineering, EPA is proposing to add the following two questions to 40 CFR 710.37(c)(2):

1. Does this particular chemical substance leave the site of manufacture or processing in any form, e.g., as product, effluent, emission? If so, what measures have been taken to guard against the discovery of its identity?

2. If the chemical substance leaves the site in a product that is available to the public or your competitors, can the chemical substance be identified by analysis of the product?

These two questions are intended to assist EPA in gathering the information it uses to evaluate confidentiality claims. They are modeled after substantiation questions that appear in EPA's existing regulations governing CBI claims for specific chemical identities that are asserted in Notices of Commencement (NOCs) (40 CFR 720.85(b)(3)(iv)(H)-(I)) and Chemical Data Reporting (CDR) submissions (40 CFR 711.30(b)(1)(viii)-(ix)). EPA proposed nearly

identical questions in the January 13, 2017 Active-Inactive proposed rule (Ref. 9) and in the April 25, 2019 CDR revisions proposed rule (Ref. 10). The first question has been modified from the version that appeared in the earlier proposed and existing rules to add “or processing,” to the first sentence, in recognition of the fact that unlike NOCs and CDR submissions, which are only filed by manufacturers, NOA forms may be filed (and hence CBI claims may be asserted and substantiated) by both manufacturers and processors. The second question is unchanged from the version that appeared in the Active-Inactive proposed rule and in the existing and proposed CDR rules. (Both questions are phrased slightly differently in the NOC regulation than in the other existing and proposed regulations.)

As indicated previously, EPA’s 2019 Proposed Rule, “Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory,” cross-referenced the substantiation questions for chemical identity CBI claims at 40 CFR 710.37(c). Under this supplemental proposed rule that cross-reference would remain unchanged, because it would include the two additional substantiation questions that EPA proposes to add to 40 CFR 710.37(c).

The proposed substantiation questions are intended to solicit information that is known to or reasonably ascertainable by the respondent (the manufacturer or processor making the CBI claim). “Known to or reasonably ascertainable by” is defined in 40 CFR 710.23 to mean “all information in a person’s possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.” EPA intends that the inquiry into whether a chemical substance can be identified by analysis of the product would be answered based on information that is known to or reasonably ascertainable by the respondent, about reasonably available analytical capabilities currently in use by the chemical industry. EPA

does not intend to require respondents to initiate a special research program to answer the inquiry, or to speculate about hypothetical analytical capabilities.

B. Who would have to answer these substantiation questions?

The additional substantiation questions in this supplemental proposed rule would apply to manufacturers and processors who requested to maintain a CBI claim for a specific chemical identity in either of two commercial activity notices submitted to EPA pursuant to the Active-Inactive Rule (40 CFR part 710, subpart B): an NOA Form A (retrospective commercial activity reporting) or an NOA Form B (forward-looking commercial activity reporting). The additional substantiation questions would also apply to manufacturers and processors who submit an NOA Form B in the future that requests to maintain a CBI claim for a specific chemical identity.

C. When would the additional substantiation be required?

Manufacturers and processors who have not yet submitted any substantiation to EPA would be required to submit answers to the two newly proposed substantiation questions at the same time as they submit the rest of their required substantiation. The substantiation deadline for those entities would depend on whether the chemical identity CBI claim was asserted in an NOA Form A or B. For persons substantiating a chemical identity CBI claim asserted in an NOA Form A, if finalized as proposed, EPA's 2019 Proposed Rule would require that all substantiations be filed not later than 90 days after the effective date of the final rule. EPA is not altering or otherwise revisiting that proposed requirement in this supplemental proposed rule. For persons substantiating a chemical identity CBI claim asserted in an NOA Form B, the Active-Inactive Rule requires that all substantiations be submitted within 30 days of submitting the NOA Form B. See 40 CFR 710.37(a)(2). That provision is currently in effect, and EPA is not proposing to amend or otherwise revisit that requirement in this supplemental proposed rule.

Manufacturers and processors who have already voluntarily submitted substantiation to EPA with an NOA Form A, or who will have submitted substantiation for a chemical identity CBI claim asserted in an NOA Form B before the revisions to 40 CFR 710.37(c) are finalized and go into effect, would be required to supplement their earlier submission with answers to the two new substantiation questions. For persons substantiating a chemical identity CBI claim asserted in an NOA Form A, EPA is proposing to require submission of the supplemental substantiation by not later than 90 days after the effective date of the final rule, consistent with the other substantiation deadlines in the 2019 Proposed Rule. For persons substantiating a chemical identity CBI claim asserted in an NOA Form B, EPA is proposing to require submission of the supplemental substantiation by not later than 30 days after the effective date of the final rule. The 30-day deadline would facilitate EPA's ability to meet the statutory requirement to "promptly" review chemical identity CBI claims asserted in an NOA Form B, see TSCA 8(b)(5)(B)(iii)(II), and would be consistent with the existing 30-day deadline for substantiation of such claims pursuant to 40 CFR 710.37(a)(2).

D. Would this impact the proposed exemption for other previously submitted substantiations?

In the 2019 Proposed Rule, EPA recognized that some persons may have recently substantiated their specific chemical identity CBI claims in other submissions to the Agency outside of the voluntary substantiation process for NOA Form A that was set forth in the Active-Inactive Rule. EPA proposed to exempt those persons from the substantiation requirement in the 2019 Proposed Rule so long as the previous substantiation was submitted less than five years before the substantiation deadline that will be set in the final rule, and the person reports to EPA certain identifying information for the previous substantiation (i.e., submission date and type, and case number, transaction ID, or equivalent identifier).

In this supplemental proposed rule, EPA is also revising the proposed exemption in the 2019 Proposed Rule to clarify that a previously submitted substantiation must contain information that is responsive to all substantiation questions in the final rule to relieve the submitter of the requirement to submit a new substantiation. In other words, to serve as a substitute for a new substantiation, EPA is proposing to require that a previously submitted substantiation must provide information that is substantively equivalent to that sought in the substantiation questions that are ultimately finalized. Substantiations of specific chemical identity CBI claims that were submitted with CDR submissions in accordance with the substantiation procedures at 40 CFR 711.30(b)(1), or with NOCs in accordance with the substantiation procedures at 40 CFR 720.85(b)(3)(iv), would be deemed by EPA as responsive to all substantiation questions in the amended 40 CFR 710.37(c), and could therefore serve as a basis for the proposed exemption. EPA expects that the vast majority of recent substantiations for specific chemical identity CBI claims submitted outside of the voluntary Active-Inactive Rule process would have been submitted pursuant to one of those two regulatory substantiation provisions. Substantiations that were not submitted pursuant to one of those two regulatory provisions (for example, substantiations for CBI claims asserted in submissions under TSCA section 8(e)) may also be responsive to all substantiation questions in the amended 40 CFR 710.37(c), but would need to be evaluated on a case-by-case basis.

E. How would EPA review CBI claims for specific chemical identity?

In the 2019 Proposed Rule, EPA explained that when reviewing CBI claims, EPA would apply the substantive criteria for confidentiality determinations set forth in 40 CFR 2.306(g) and 2.208. See Ref. 4 at 16830. The Active-Inactive Rule likewise incorporated these substantive criteria for confidentiality determinations. See 40 CFR 710.37(a) (referencing the 40 CFR part

2, subpart B procedures for treatment and disclosure of information claimed as confidential). EPA is not proposing to change either the 2019 Proposed Rule or the Active-Inactive Rule (40 CFR 710.37(a)) in this regard. EPA interprets the substantive criteria described in 40 CFR 2.208 and cross-referenced in 40 CFR 2.306(g) to already encompass consideration of a specific chemical identity's susceptibility to reverse engineering.

Specifically, 40 CFR 2.208(c) provides that one of the required criteria for approval of a confidentiality claim is that “[t]he information is not, and has not been, reasonably obtainable without the business’s consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding).” If a specific chemical identity is readily discoverable through reverse engineering, then that chemical identity is reasonably obtainable without the business’s consent by other persons by use of legitimate means, and the specific chemical identity would not be entitled to confidential treatment.

EPA notes that on June 24, 2019, the U.S. Supreme Court issued a decision addressing the test for determining whether commercial information qualifies as “confidential” for purposes of Exemption 4 of the Freedom of Information Act (FOIA), 5 U.S.C. 552(b)(4). *See Food Marketing Institute v. Argus Leader Media*, 139 S. Ct. 2356 (2019). The Court found that, “[a]t least where commercial or financial information is both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy, the information is ‘confidential’ within the meaning of Exemption 4.” 139 S. Ct. at 2366. The Court rejected the “substantial competitive harm” test that had long been applied by many courts of appeals, under which certain commercial information could not be deemed “confidential” unless disclosure was likely to cause substantial harm to the competitive position of the person

from whom the information was obtained. *Id.* at 2361, 2364-66. A copy of the Court’s opinion is available in the docket for this action.

Because TSCA section 14(a) incorporates FOIA Exemption 4 as the basic framework for determining whether information is eligible for protection from disclosure under TSCA, the substantive criteria for TSCA confidentiality determinations include the “substantial competitive harm” test that courts of appeals had formerly applied under FOIA Exemption 4. See 15 U.S.C. 2613(a), 40 CFR 2.306(g), and 40 CFR 2.208(e)(1). In light of the recent Court decision, EPA is considering whether revisions are warranted to EPA’s substantive review criteria for CBI claims not submitted under TSCA. However, EPA is not proposing to remove the “substantial competitive harm” review criterion or any related substantiation question for the TSCA CBI claims addressed in this rulemaking, because Congress amended TSCA section 14 in 2016 to specifically require any person asserting a CBI claim under TSCA to include a certified statement that the person has “a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person.” TSCA section 14(c)(1)(B)(iii), (c)(5); see also TSCA section 14(c)(1)(C)(ii)(II) (referencing substantial competitive harm).

IV. Request for Comments

EPA is seeking public comment on all aspects of this supplemental proposed rule, including the proposed two additional substantiation questions, the proposed revisions to the proposed exemptions from substantiation requirements, the proposed procedures for supplementing previously-submitted substantiations, and whether EPA has appropriately addressed the federal circuit court decision. EPA is seeking comment only on the issues discussed in this supplemental proposed rule and is not reopening comment on any other aspects

of the 2019 Proposed Rule or the Active-Inactive Rule. Public comments on the 2019 Proposed Rule that were submitted to the docket by the end of the comment period for that proposed rule (i.e., June 24, 2019) will be considered by EPA and addressed in the final rule.

V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these references and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical contact listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. TSCA Inventory Notification (Active-Inactive) Requirements; Final Rule. Federal Register, 82 FR 37520, August. 11, 2017 (FRL-9964-22).
2. EPA. Notice of Activity Form A; Final, 2017.
3. EPA. Notice of Activity Form B; Final, 2017.
4. EPA. Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory; Proposed Rule. Federal Register, 84 FR 16826, April 23, 2019 (FRL-9992-05).
5. EPA. Memorandum from Laura Nielsen to Scott Sherlock, *Burden and Cost Estimates for the Supplemental Notice of Proposed Rulemaking: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory (Docket # EPA-HQ-OPPT-2018-0320)*, 2019.
6. EPA. ICR No. 2594.01 *Information Collection Request Proposed Addendum to TSCA Review Plan CBI Substantiation Supporting Statement for a Request for OMB Review under the Paperwork Reduction Act*. 2019.
7. EPA. ICR No. 2565.03 *Information Collection Request Proposed Addendum to TSCA*

Section 8(b) Reporting Requirements for TSCA *Inventory Supporting Statement for a Request for OMB Review under the Paperwork Reduction Act*. 2019.

8. EPA. Economic Analysis for the Proposed Rule: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory, 2019.

9. TSCA Inventory Notification (Active-Inactive) Requirements; Proposed Rule. Federal Register, 82 FR 4255, January 13, 2017 (FRL-9956-28).

10. TSCA Chemical Data Reporting Revisions and Small Manufacturer Definition Update for Reporting and Recordkeeping Requirements Under TSCA Section 8(a); Proposed Rule. Federal Register, 84 FR 17692, April 25, 2019 (FRL-9982-16).

11. EPA. *Small Entity Analysis Report for the Final Rule: TSCA Inventory Notification Requirements*, 2017.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <http://www2.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket for this action as required by section 6(a)(3)(E) of Executive Order 12866.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is expected to be subject to the requirements for regulatory actions specified

in Executive Order 13771 (82 FR 9339, February 3, 2017). EPA prepared an analysis of the estimated costs and benefits associated with this action (Ref. 5), which is available in the docket and is summarized in Unit I.E.

C. Paperwork Reduction Act (PRA)

The information collection activities in this supplemental proposed rule have been submitted for approval to OMB under the PRA, 44 U.S.C. 3501 *et seq.* EPA prepared a supplement to the Information Collection Request (ICR) document that was submitted for the 2019 Proposed Rule, which has been assigned EPA ICR No. 2594.02 and OMB Control No. 2070-[New] (Ref. 6). The information collection activities contained in the Active-Inactive Rule are approved by OMB under EPA ICR No. 2565.01 and OMB Control No. 2070-0201 (Ref. 7). You can find a copy of the ICRs in the docket for this rule, and the incremental paperwork burden is briefly summarized here.

The incremental reporting requirements identified in this supplemental proposed rule involve the addition of two substantiation questions that would provide EPA with information necessary to evaluate confidentiality claims and determine whether the claims qualify for protection from disclosure. Since the incremental burden impacts both ICRs, the summary is presented in Table 2.

Table 2: Incremental Paperwork Burden Estimates

<i>EPA ICR No.:</i>	2565.01	2594.02
<i>OMB Control No.:</i>	2070-0201	2070-[new]
<i>Rulemaking:</i>	Active-Inactive Rule	2019 Proposed Rule
<i>ICR Activities:</i>	Ongoing annual burden/cost (forward looking).	One-time burden/cost.
<i>Respondents/affected entities:</i>	Persons who manufacture or process chemical substances and submit a Form B with chemical identity substantiation requirements.	Persons who manufacture or process chemical substances and submit a Form A with chemical identity substantiation requirements.

<i>Respondent's obligation to respond:</i>	Mandatory.	Mandatory.
<i>Frequency of response:</i>	On-occasion.	Once per chemical.
<i>Estimated total number of respondents:</i>	1	275
<i>Estimated burden per respondents:</i>	0.4 hours per year	4 hours
<i>Estimated total burden:</i>	0.4 hours	1,123 hours (one time)
<i>Estimated costs per respondent:</i>	\$29	\$317
<i>Estimated total costs:</i>	\$29 per year	\$87,054

Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations in 40 CFR is consolidated in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to EPA using the docket identified at the beginning of this supplemental proposed rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to OIRA_submission@omb.eop.gov, Attention: Desk Officer for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**]. EPA will respond to any ICR-related comments in the final rule.

D. Regulatory Flexibility Act (RFA)

Pursuant to RFA section 605(b), 5 U.S.C. 601 *et seq.*, I certify that this action will not

have a significant economic impact on a substantial number of small entities. The small entities subject to the requirements of this supplemental proposed rule are manufacturers (including importers) and processors of chemical substances. In this supplemental proposed rule, impacts on these small entities are evaluated qualitatively and with respect to the two rules in which small entity impacts are assessed in the small entity analyses (SEAs) prepared for the Active-Inactive Rule (Ref.11) and for the 2019 Proposed Rule (Ref. 8). The estimated incremental impact on small entities associated with this supplemental proposed rule are presented in the Cost Memo (Ref.5), which is in the public docket for this action. In that analysis, EPA explains how each component of this supplemental proposed rule does not have a significant economic impact on a substantial number of small entities, and moreover how the combination of the components does not have a significant economic impact on a substantial number of small entities.

In the small entity analysis (SEA) for the NPRM for this proposed rule, EPA found that no small entities from Groups (2) and (3) would experience an impact of greater than 1% of revenues. The same respondents are considered for Groups (2) and (3) for this component of this SNPRM, but at a much lower average incremental cost per respondent. Therefore, the same conclusion from that SEA applies to the corresponding small entities in Groups (2) and (3) potentially affected by this SNPRM.

In the SEA for the Active-Inactive rule, the most burdensome average unit compliance cost selected for assessment was associated with manufacturers (including importers) submitting Form As in the start-up reporting period. The small entities in Group (1) for this SNPRM are drawn from Form A submitters identified in the Active-Inactive rule. Using that reporting group as a basis, EPA found in that SEA that no small entities would experience an impact of greater than 1% of revenues. The Group (1) small entities for this component of the SNPRM represent a

subset, and therefore lower number of small entities than evaluated in the most affected group in that SEA. Moreover, EPA reasonably assumes for purposes of this SNPRM SEA that the small entity impacts for this component of this SNPRM associated with Group (1) respondents involve a similar impacts distribution as for the Active-Inactive Form A start-up reporters. Given these considerations and additionally the much lower average incremental cost per respondent in this SNPRM compared to the Active-Inactive rule Form A start-up reporters, the conclusion from the Active-Inactive rule SEA applies to the corresponding small entities in Group (1) potentially affected by this SNPRM.

Similarly, small entities submitting a Form B under the Active-Inactive rule would incur a much lower average incremental cost per respondent than in the Active-Inactive rule's SEA, and therefore the conclusion from the Active-Inactive rule SEA applies to the corresponding small entities potentially affected by this SNPRM.

Considering impacts on small businesses from the components presented in this unit, the information from each component is combined to support the conclusion that the overall impact of this action is minimal and would have no significant economic impact on a substantial number of small entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action is not expected to impose enforceable duty on any state, local or tribal governments, and the requirements imposed on the private sector are not expected to result in annual expenditures of \$100 million or more for the private sector. As such, EPA has determined that the requirements of UMRA sections 202, 203, 204, or 205 do not apply to this action.

F. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. Thus, EO 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997), as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of Executive Order 13045 has the potential to influence the regulation. This action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a “significant energy action” as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on energy supply, distribution, or use.

J. National Technology Transfer and Advancement Act (NTTAA)

Since this action does not involve any technical standards, NTTAA section 12(d), 15 U.S.C. 272 note, does not apply to this action.

K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994), because it does not establish an environmental health or safety standard. This action establishes an information requirement and does not affect the level of protection provided to human health or the environment.

List of Subjects in 40 CFR Part 710

Environmental Protection, Chemicals, Confidential Business Information, Hazardous substances, Reporting and Recordkeeping Requirements.

Dated: October 24, 2019.

Andrew R. Wheeler,

Administrator.

Therefore, it is proposed that 40 CFR chapter I, part 710, subpart B be amended and 40 CFR chapter I, part 710, subpart C, as proposed to be added at 84 FR 16833 (April 23, 2019), be amended as follows:

PART 710—COMPILATION OF THE TSCA CHEMICAL SUBSTANCE INVENTORY

1. The authority citation for part 710 continues to read as follows:

Authority: 15 U.S.C. 2607(a) and (b).

Subpart B—Commercial Activity Notification

2. Amend §710.37 by adding paragraph (a)(2)(i), and revising paragraph (c)(2) to read as follows:

§ 710.37 Confidentiality claims.

(a) * * *

(2) * * *

(i) Persons who submitted the information described in paragraph (a)(2) of this section before [EFFECTIVE DATE OF THE FINAL RULE] must submit answers to the questions in paragraphs (c)(2)(ii) and (iii) of this section not later than [DATE 30 CALENDAR DAYS AFTER EFFECTIVE DATE OF THE FINAL RULE].

(ii) [Reserved].

* * * * *

(c) * * *

(2) *Substantiation for confidentiality claims for chemical identity.*(i) Is the confidential chemical substance publicly known to have ever been offered for commercial distribution in the United States? If you answered yes, explain why the information should be treated as confidential.

(ii) Does this particular chemical substance leave the site of manufacture or processing in any form, e.g., as product, effluent, emission? If so, what measures have been taken to guard against the discovery of its identity?

(iii) If the chemical substance leaves the site in a product that is available to the public or your competitors, can the chemical substance be identified by analysis of the product?

* * * * *

Subpart C—Review Plan

3. Amend §710.43(b), as proposed to be added at 84 FR 16833 (April 23, 2019), by revising paragraph (b)(1) and paragraph (b)(2) introductory text to read as follows:

§ 710.43 Persons subject to substantiation requirement.

* * * * *

(b) *Exemptions.* (1) Any person who completed the voluntary substantiation process set forth in § 710.37(a)(1) is exempt from the substantiation requirement of this subpart pertaining to the submission of answers to the questions in § 710.37(c)(1) and (2)(i). All remaining requirements of § 710.45 must be met in accordance with the deadline specified in § 710.47(a), including the requirement to submit answers to the questions in 710.37(c)(2)(ii) and (iii), signed and dated by an authorized official, and to complete the certification statement in § 710.37(e).

(2) A person who has previously substantiated the confidentiality claim for a specific chemical identity that the person requested to maintain in a Notice of Activity Form A, by submitting information that is responsive to all questions in § 710.37(c)(1) and (2), is exempt from the substantiation requirement of this subpart if both of the following conditions are met:

4. Revise §710.47(a), as proposed to be added at 84 FR 16833 (April 23, 2019), to read as

follows:

§ 710.47 When to submit substantiation or information on previous substantiation.

- (a) All persons required to substantiate a confidentiality claim pursuant to § 710.43(a) or
- (b)(1) must submit their substantiation not later than [DATE 90 CALENDAR DAYS AFTER THE EFFECTIVE DATE OF THE FINAL RULE].

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[FR Doc. 2019-23714 Filed: 11/7/2019 8:45 am; Publication Date: 11/8/2019]